**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br><br>**WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DEFENSE EXPERT SAMANTHA J. PULLIAM, M.D.**

NOW COME Plaintiffs, by and through undersigned counsel, and respectfully submit this Reply in support of Pls.' Mot. to Exclude Certain Ops. and Test. of Defense Expert Samantha J. Pulliam, M.D. [ECF No. 3623] (hereinafter "Mot.") and Mem. of Law in Supp. of Pls.' Mot. to Exclude Certain Ops. and Test. of Defense Expert Samantha J. Pulliam, M.D. [ECF No. 3627] (hereinafter "Mem.").

## ARGUMENT

### I. Opinions regarding cytotoxicity, degradation, curling or fraying, and particle loss should be excluded because Dr. Pulliam is unqualified to render such opinions.

Defendants first respond that Plaintiffs "gloss[ed] over Dr. Pulliam's extensive professional education, training, and experience, erroneously contending that it is 'devoid of any experience translating' laboratory results 'into clinical effect[.]'" (Resp. to Pls.' Mot. to Exclude Certain Ops. and Test. of Defense Expert Samantha J. Pulliam, M.D. (hereinafter "Resp.") [ECF No. 3764] at 2.) To be entirely clear, Plaintiffs did not argue that Dr. Pulliam is devoid of any experience translating laboratory results into clinical effect, they argued that "her background is

devoid of any experience translating laboratory *cytotoxicity test* results into clinical effect." Regardless, Plaintiffs did not mention Dr. Pulliam's internship in Anatomic Pathology because it is irrelevant to cytotoxicity and polypropylene mesh. In fact, Dr. Pulliam herself testified that during this 1-year internship she neither studied explanted polypropylene mesh nor gained any sort of knowledge of the same. (Mot. Ex. D, a true copy of the 3/31/2017 deposition transcript of Samantha J. Pulliam, M.D. (hereinafter "Pulliam Dep. Tr.") at 56:21-25.)

Defendants' then argue that Plaintiffs' argument is circular because, by its logic, "no physician would be qualified to opine that mesh is not cytotoxic because the only person who is qualified is someone who has encountered evidence in their clinical practice suggesting that mesh *is* cytotoxic." (Resp. at 3.) However, Plaintiffs' argument is not simply that Dr. Pulliam is unqualified because she has never encountered cytotoxicity as a complication associated with mesh. Rather, Plaintiffs' argument is that Dr. Pulliam has no toxicological experience whatsoever; that Defendants themselves have previously sought exclusion based on this very point, but the same was denied by this Court because even if not a toxicologist, the expert stated he regularly encountered cytotoxicity in his practice and has removed mesh explants, including TVT, due to cytotoxicity; and, Dr. Pulliam is neither a toxicologist nor has she ever encountered cytotoxicity in her practice or removed mesh due to cytotoxicity. (Mem. at 5.) In other words, Dr. Pulliam is not a toxicologist, nor has she encountered cytotoxicity in her practice or removed mesh due to cytotoxicity, which have been held by this Court to qualify an expert even when not a toxicologist—a saving grace of sorts that is not present here.

Defendants' last argument is that "an expert is not required personally to perform studies and experiments to opine on a matter. As this Court has found, when an expert relies on scientific literature, as well as her own knowledge and experience, *her opinion is considered reliable*."

(Resp. at 3) (emphasis added) (citing *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 626 (S.D. W. Va. 2013).) First, the holding cited by Defendants relates to reliability, not qualification. Second, Plaintiffs do not assert that an expert must personally perform studies and experiments to opine on a matter. Rather, Plaintiffs assert specific examples to demonstrate Dr. Pulliam's lack of knowledge, experience and, thus, expertise. (*See* Mem. 4-6; 7-8.)

Since Defendants seemingly do not respond to Plaintiffs' arguments regarding Dr. Pulliam's lack of qualification to opine to degradation, curling or fraying, and particle loss, Plaintiffs similarly will not address these issues here and, instead, respectfully direct the Court to their original arguments concerning the same. (*See id.* at 7-8.)

## II. Opinions regarding cytotoxicity, degradation, curling or fraying, and particle loss should be excluded because such opinions are unreliable.

Plaintiffs also seek to exclude as unreliable Dr. Pulliam's opinions regarding cytotoxicity, degradation, curling or fraying, and particle loss.

Contrary to Defendants' response, Plaintiffs argument regarding cytotoxicity is not simply that Dr. Pulliam "failed to *specifically identify all* of the medical literature upon which she relied in forming her opinions." (Resp. at 4) (emphasis added). Plaintiffs' argument is also that Dr. Pulliam did not describe her process or method for extrapolating underlying, separate studies to reach her ultimate opinion that prolene mesh is not cytotoxic, thereby making it impossible to know not only the methodology and reliability of the underlying studies themselves, but also whether her extrapolation and analytical method was based on reliable methodology and the scientific method. (Mem. at 6.) Thus, Dr. Pulliam's cytotoxic opinion should be excluded as unreliable. *See Konrick v. Exxon Mobil Corp.*, No. CV 14–524, 2016 WL 439361, at *13 (E.D. La. Feb. 4, 2016) ("Without any explanation of [the expert's] methodology or application of her

analytical methods to the literature, the report does not provide a reliable basis for [the expert's] opinion.").

Similarly, Plaintiffs' argument is not simply that Dr. Pulliam's opinions regarding degradation is unreliable because of *one* study as Defendants allege, (Resp. at 4), but that the Ford Cochrane Review that Dr. Pulliam herself specifically cites as "excellent medium and long-term results" and then uses to dismiss the Clave study states in multiple different sections that long-term results is a limitation of the review and that long-term effects have not been established. Plaintiffs did not choose to use this review, Dr. Pulliam did; and, Dr. Pulliam did not use this in a general reliance sense, but specifically cites to the purported long-term effects therein to discredit the Clave study and to reach a conclusion the Clave study did not reach (i.e., surface cracking does not correspond to functional compromise). Moreover, Plaintiffs' arguments do not "go solely to the weight a jury should" afford as Defendants contend in their response, (*id.* at 4-5), because Plaintiffs argument is that the Ford review Dr. Pulliam explicitly relies upon affirmatively states that long-term efficacy is a limitation of the review and has not been established, not that Dr. Pulliam failed to review or cite a particular document. Since Defendants did not address Plaintiffs' arguments concerning the unreliable methodology Dr. Pulliam utilized to reach her degradation opinions, Plaintiffs will not do so in this Reply and, instead, respectfully direct the Court to their original arguments regarding the same. (*See* Mem. at 9-10.)

Finally, as Defendants did not specifically respond to Plaintiffs' reliability arguments regarding Dr. Pulliam's curling or fraying and particle loss opinions, Plaintiffs will not address these in this Reply and, instead, respectfully direct the Court to their original arguments concerning the same. (*See* Mem. at 13-14.)

## III. Dr. Pulliam is unqualified to opine that polypropylene is the best material available, but even if qualified, this opinion is unreliable.

Regarding qualification, Defendants only respond that "Plaintiffs essentially argue that only a biomaterials or polymer science expert can offer the opinion that polypropylene has been found to be the 'best' material available for slings." (Resp. at 5.) However, this is a gross simplification and mischaracterization of Plaintiffs' arguments. Plaintiffs do not argue that *only* a biomaterials or polymer science expert may render this opinion, but rather, that the proffered expert must be qualified "by knowledge, skill, experience, training, or education" in the topic she seeks to opine, Fed. R. Evid. 702; and, Dr. Pulliam is not qualified to render this opinion, as evidenced by her own testimony, (Mem. at 11-12). Moreover, Dr. Pulliam does not opine that "polypropylene *has been found* to be the 'best' material available" as Defendants contend, (Resp. at 5) (emphasis added), she opines that "polypropylene *is* the best available material for slings," (Mot. Ex. B, TVT and TVT-O Expert Report of Samantha J. Pulliam, M.D. (hereinafter "Report") at 15) (emphasis added). Since Defendants did not respond in any other way to Plaintiffs' qualification arguments regarding this opinion, Plaintiffs will not rehash their Memorandum and, instead, respectfully direct the Court to their original arguments concerning the same. (*See* Mem. at 10-12.)

Defendants' own response to the reliability of this opinion supports exclusion. Defendants contend that the opinion is reliable because Dr. Pulliam cites to relevant literature and "where an expert's opinion is based, not only upon his or her personal clinical or scientific experience, but also on his or her review of the relevant literature, the opinion is reliable and admissible." (Resp. at 5) (citing *In re C.R. Bard, Inc.*, 948 F. Supp. at 626.) However, as addressed above and in Plaintiffs' Mem., Dr. Pulliam does not have personal clinical or scientific experience; she is not qualified to render this opinion. Therefore, the very rule cited by Defendants supports exclusion because it requires the opinion be based on personal clinical or scientific experience *and* on the expert's review of the relevant literature, but Dr. Pulliam's opinion is not based on the former

because she has no personal clinical or scientific experience. Lastly, Defendants contend that Dr. Pulliam cited Amid (1997) and Ford (2015) on pages 13-14 of her report to support this opinion, which is on page 15 and under a different subsection heading than pages 13-14, to support "her opinion that polypropylene is the most favored and studied material for use in slings to treat stress urinary incontinence," (Resp. at 5). It bears repeating again, though, that Dr. Pulliam's opinion, as she stated in *her* report, is not simply that polypropylene is the most favored and studied material, but rather, that it "is the *best* available material for slings." (Mot. Ex. B, Report at 15) (emphasis added.)

**IV. Opinions regarding the IFU should be excluded because such opinions are beyond her expertise and are improper.**

Defendants respond that "Plaintiffs misunderstand the scope of the opinions offered" because "Dr. Pulliam does not, as Plaintiffs suggest, examine the text of each IFU and offer the 'legal conclusion' that such warnings are legally adequate." (Resp. at 6.) Dr. Pulliam lists some of the instructions included in the IFUs, which she states are "[b]ased on guidance from the FDA," defines TVT as a prescription device, and then quotes from federal regulations to conclude that it is a device "for which 'adequate directions for use' (21 CFR 801.5) cannot be prepared (FDA Device Labeling Guidance #G91-1)." (Mot. Ex. B, Report at 25) (emphasis in original.) This is applying the law to the facts and is, therefore, impermissible. *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

Defendants then cursorily contend that "Dr. Pulliam is qualified by her knowledge, skill, education, training, and clinical experience, as well as her review of medical literature." (Resp. at 6.) However, Defendants do not address this alleged qualification in light of Dr. Pulliam's own testimony establishing her utter lack of experience in regulatory affairs or product warnings. (*See*

Mot. Ex. D, Pulliam Dep. Tr. at 85:21-25; 154:24-155:4; 231:15-232:3; *see also* Mem. at 14-15.) Furthermore, Dr. Pulliam's opinions encompass more than just "how physicians utilize product IFUs in their clinical practice[,] what information a physician expects to be included in product IFUs to enable him or her to safely utilize the product[,] and what risks associated with the use of TVT and/or TVT-O are generally known by pelvic floor surgeons as compared to those risks that she would rely upon an IFU to identify" as Defendants argue. (Resp. at 6-7.) Indeed, Dr. Pulliam testified that it is her opinion that the IFUs as prepared by Ethicon are adequate, (Mot. Ex. D, Pulliam Dep. Tr. at 232:12-19), and Defendants have not addressed what additional expertise Dr. Pulliam possesses "to offer expert testimony about what information should or should not be included in an IFU," *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2017 WL 1175399, at *4 (S.D.W. Va. Mar. 29, 2017) ("While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.") (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015)). Lastly, if Dr. Pulliam is not opining as to what should or should not be included in an IFU, then why did she even discuss 21 C.F.R. 801.109(c), which states that certain risks and information may be omitted from certain product labeling, let alone state that it is support for her opinions. (*See* Mot. Ex. B, Report at 27.)

**V. Opinions regarding training and teaching should be excluded because such opinions are: beyond her expertise, unreliable, irrelevant, and improper.**

Defendants cursorily conclude that "[s]imply put, Dr. Pulliam is qualified—by education, skill, experience, training, and her review of medical literature and professional education materials—to offer the[se] opinions." (Resp. at 8.) Yet, Defendants do not state why or how she is qualified to opine on the training offered by Ethicon when she has never proctored or even

attended an Ethicon training session for TVT or TVT-O. Although Dr. Pulliam may have "experience attending such trainings generally—whether or not sponsored by Ethicon," (*id.*), Dr. Pulliam seeks to opine on the adequacy of *Ethicon* training, not the training provided by other manufacturers.

Similarly, while Defendants argue that these opinions are "a continuation of Dr. Pulliam's opinions with respect to the product IFUs," (*id.* at 7), Dr. Pulliam seemingly does not treat these opinions as a continuation when some are contained four pages and five bolded sections after the IFU section, (s*ee generally* Mot. Ex. B, Report at 25-29.) Nevertheless, Defendants do not respond to Plaintiffs' arguments regarding Dr. Pulliam's failure to describe any basis for these opinions. Dr. Pulliam may cursorily list the general topics or components of an Ethicon training session, but she does not provide *how* these components or the information taught therein adequately train physicians; this may very well be because she simply does not know as she has never attended an Ethicon training session for TVT or TVT-O. In short, if a proffered opinion regarding the inadequacy of training has been held "unreliable because [the expert] fails to describe the basis for his opinion that Ethicon's training was inadequate," *see Edwards*, 2014 WL 3361923, at *10, then Dr. Pulliam's failure to describe the basis for her opinions that Ethicon's training was adequate should similarly render the opinions unreliable.

Defendants argue that Dr. Pulliam's opinions are reliable because she mentioned "the MAUDE database as *a* source of support for her opinions—not the *sole* or even primary source." (Resp. at 8) (emphasis in original.) Dr. Pulliam, though, has not identified her primary source, meaning it could very well be the MAUDE database. Regardless, Dr. Pulliam's testimony and the report itself demonstrate the reliance she placed on the low complication rate reported in the MAUDE database. For example, in her report, Dr. Pulliam states that MAUDE "tracks

complications, as the TVT and TVT-O are classified as medical devices. This is unlike any other treatment for stress urinary incontinence, even though both pubovaginal slings and urethropexies often use prolene sutures-the same substance as TVT mesh." (*See* Mot. Ex. B, Report at 28.) Dr. Pulliam seemingly opines that TVT and TVT-O are safe because the complication rate can be tracked whereas other treatments of SUI, even those which use prolene sutures, cannot be tracked. In short, Dr. Pulliam asserts the purported low complication rate of TVT and TVT-O as proof that the devices are safe and adequate training is provided by Ethicon, and she based this allegedly low complication rate on the rate reported in the MAUDE database. Thus, Dr. Pulliam's opinions should be excluded as unreliable.

In addition to qualification and unreliability due to Dr. Pulliam's reliance on the MAUDE database, Plaintiffs also challenged Dr. Pulliam's opinions regarding training and teaching on the grounds that they are irrelevant to the issues, unhelpful to the jury, and relate to Ethicon's state of mind, corporate conduct, and intent. (*See* Mem. at 18-20.) However, as Defendants did not respond to these arguments, Plaintiffs will not rehash their Memorandum and, instead, respectfully direct the Court to their original arguments concerning the same. (*Id.*)

## VI. Opinions constituting legal conclusions should be excluded because such opinions are improper expert testimony.

Finally, Plaintiffs move for the exclusion of all proffered legal conclusions, such as "the idea that TVT/TVT-O is unreasonably dangerous for its intended use" is not supported by professional society statements. Defendants argue that this is not a legal conclusion or opinion at all, but rather, that "[i]n further support of the opinions offered throughout her report, which were based upon and supported by her clinical experience and review of relevant and reliable scientific literature, Dr. Pulliam cited to industry guidelines and standards that entirely belie and refute Plaintiffs' experts' opinions that TVT and TVT-O are unsafe due to defects in the design of the

products." (Resp. at 9.) Also, that "Plaintiffs are improperly and erroneously trying to put words in Dr. Pulliam's mouth and unasserted opinions in her Report." (*Id.*)

With respect, however, it is seemingly Defendants who seek to put words in Dr. Pulliam's mouth because nowhere in this sentence, or even in this section, does Dr. Pulliam state that she cites to these industry guidelines and standards in order to belie and refute Plaintiffs' experts' opinions that TVT and TVT-O are unsafe due to defects in the design of the products. Rather, she states that these guidelines and standards "do not support the idea that TVT/TVT-O is unreasonably dangerous for its intended use." (Mot. Ex. B, Report at 25.) In other words, Dr. Pulliam cites these materials to support her *opinion* that TVT and TVT-O are not "unreasonably dangerous." This is the ultimate issue for the jury to decide. Even assuming *arguendo* that Dr. Pulliam's intent was to belie and refute Plaintiffs' experts, it is still an opinion – Dr. Pulliam is opining that the TVT and TVT-O are not "unreasonably dangerous," thereby rendering Plaintiffs' experts' wrong. If Plaintiffs' experts opined that TVT and TVT-O are unsafe and Dr. Pulliam contends that this opinion is wrong, such contention is an opinion. And, Dr. Pulliam does so using a legal term of art. *See Mathison*, 2015 WL 2124991, at *3 ("An expert may not state his opinion using 'legal terms of art,' such as 'defective,' '*unreasonably dangerous*,' or 'proximate cause.'") (emphasis added). Thus, this and other legal conclusions should be excluded.

## CONCLUSION

For the foregoing reasons, as well as the reasons set forth in Plaintiffs' Mot. and Mem., Plaintiffs respectfully request that their Mot. be granted.

This 4th day of May, 2017.

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PLAINTIFFS' STEERING COMMITTEE

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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## CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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PLAINTIFFS' STEERING COMMITTEE